ORAL ABSTRACT WEBCAST

TCT-6

Impact of Diabetes Mellitus on the Effectiveness of Aspirin Versus Clopidogrel as a Chronic Maintenance Antiplatelet Monotherapy After Percutaneous Coronary Intervention: Results From the HOST-EXAM Trial

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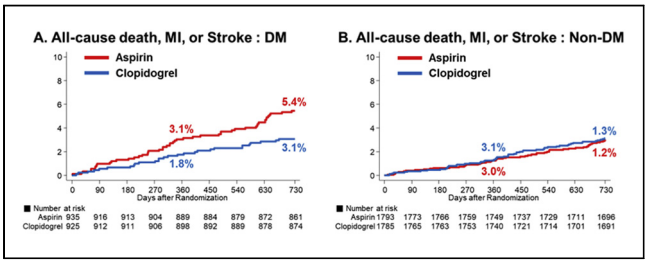
BACKGROUND The Extended Antiplatelet Monotherapy (HOST-EXAM) randomized trial reported a significant risk reduction of clopidogrel monotherapy compared with aspirin for the 2-year composite primary endpoint of all-cause death, nonfatal myocardial infarction (MI), stroke, readmission due to acute coronary syndrome, and major bleeding in patients who had completed the dual antiplatelet therapy (DAPT) after coronary stenting. In this pre-specified subgroup analysis, we investigated whether this result is consistent in patients with diabetes mellitus (DM).

METHODS The study population included patients who received DAPT without any clinical event for 12 ± 6 months after coronary stenting. We randomized patients to clopidogrel or aspirin monotherapy group in a 1:1 ratio and stratified by the presence of DM. The primary endpoint was a composite of all-cause death, MI, and stroke at 2 years.



RESULTS The rate of the primary composite endpoint was significantly lower in the clopidogrel group compared with the aspirin group (5.4% vs 3.1%; hazard ratio: 0.56 [0.35-0.89]; $P = 0.014$) in patients with diabetes, whereas the rate was similar in nondiabetic patients, showing significant interaction (P for interaction = 0.040). The results were mainly driven by the significant risk reduction of MI and stroke in the clopidogrel group for patients with diabetes. The type of treatment or the control status of DM did not affect the results significantly.

CONCLUSION As a chronic maintenance after DAPT for coronary stenting, clopidogrel monotherapy significantly reduced the 2-year risk of the composite of all-cause death, MI, and stroke only in patients with diabetes compared with aspirin monotherapy.

CATEGORIES CORONARY: Pharmacology and Pharmacotherapy

TCT-7

Two-Year Results of the OPTIMIZE IDE Trial: A Randomized Evaluation of Sirolimus-Eluting Coronary Stents With Fixed-Wire and Rapid-Exchange Delivery Systems and a Novel Bioresorbable Drug Carrier

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BACKGROUND The ultra-low profile Slender integrated delivery system (IDS) (Svelte Medical System) fixed-wire and rapid-exchange (Direct RX) drug-eluting stent (DES) systems, specifically designed to facilitate transradial (TR) access and direct stenting (DS), were evaluated for safety and efficacy in the prospective, randomized, controlled, multicenter OPTIMZE IDE trial.

METHODS OPTIMIZE compared Slender IDS or Direct RX with Xience (Abbott Laboratories) or Promus EES (1:1 randomization) (Boston Scientific) in subjects with ischemic heart disease and ≤ 3 de novo stenotic lesions ≤ 34 mm in length in ≤2 native coronary arteries with renovascular disease (RV 2.25 mm to 4.00mm. Randomization was stratified by planned stent strategy (DS or pre-dilation) following diagnostic angiography. DS was limited to 30% of subjects. TR access was encouraged but not required. The study primary endpoint, 1-year target lesion failure (TLF), was powered for noninferiority using a creatine kinase (CK)-MB-based definition of target- vessel myocardial infarction (TVMI).

RESULTS Subjects (N = 1,639) were randomized at 74 investigative sites in the United States, Europe, and Japan; 79% were treated via TR approach. DS was successful in 94% of lesions attempted with a DS strategy. TLF at 1 year was similar across groups (10.3% vs 9.5% for treatment and control; perineural noninferiority [PNI] = 0.034); however, noninferiority (PNI ≤ 0.025) was not met as high troponin use and subsequent protocol-defined TVMI rates effectively underpowered the study. At 1-year follow-up, rates of target lesion revascularization (1.5% vs 1.9%), TVMI (9.4% vs 8.2%), cardiac death (0.3% vs 0.3%), and any stent thrombosis (0.4% vs 0.5%) were similar across the treatment and control groups (all $P > 0.05$). Two-year outcomes, analysis of specific biomarkers, and protocol definition impact on TVMI rates will be presented for the first time.